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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,755	12/24/2001	Bernhard H. Weigl	660115.412	3719
25742	7590	06/30/2004	EXAMINER	
JERROLD J. LITZINGER 2134 MADISON ROAD CINCINNATI, OH 45208			SINES, BRIAN J	
			ART UNIT	PAPER NUMBER

1743

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/035,755	WEIGL ET AL.	
	Examiner	Art Unit	
	Brian J. Sines	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers.

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

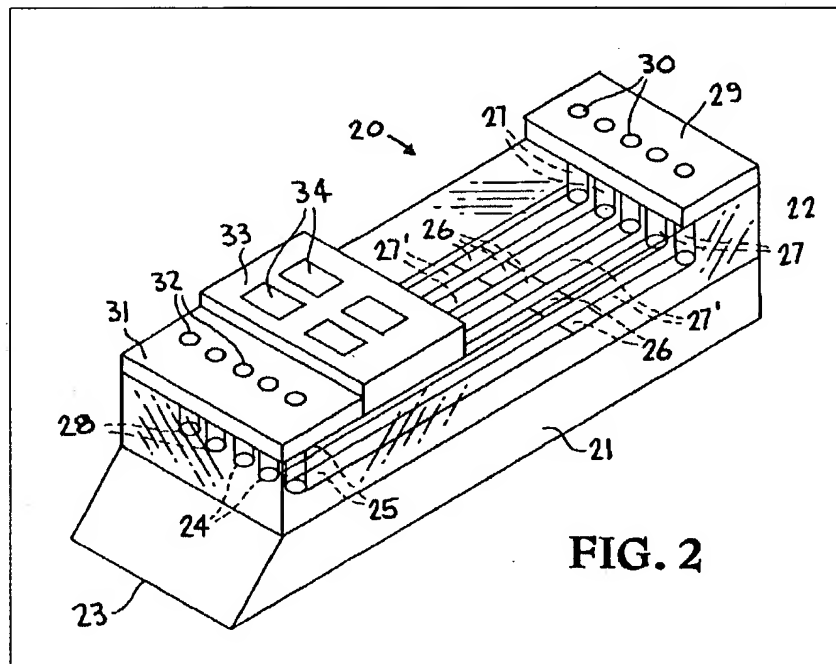
A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1 – 13 and 17 – 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Krulevitch et al. (U.S. Pat. No. 6,454,759 B2). Regarding claims 1, 6 – 11 and 19, Krulevitch et al. teach an implantable microfluidic apparatus comprising: a body structure (20) having at least one microchannel (24) with an associated fluid driving means (26); a microelectronic chip comprising circuitry (33 & 34) for operating the apparatus located within the body structure and which is capable of being coupled to an external power source without physical contact and which is also capable of being remotely monitored and controlled (see col. 3, line 10 – col. 7, line 67; figure 2). Regarding claims 2, 13 and 19, Krulevitch et al. teach the use of RF-powered electronics for remote control and programming (see col. 3, lines 52 – 63). Regarding claims 3 – 5 and 12, Krulevitch et al. teach the use of inductive electromagnetic power coupling for the implanted apparatus for the integrated electronics (see col. 3, lines 10 – 33). Regarding claims 17 and 18, Krulevitch et al. teach the incorporation of a means (32) for delivering a chemical substance (see col. 5, lines 1 – 23). The Courts have held that apparatus claims must be structurally distinguishable from the prior art in terms of structure, not function. See *In re Danley*, 120 USPQ 528, 531 (CCPA 1959); and

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Hewlett-Packard Co. v. Bausch and Lomb, Inc., 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). The Courts have held that the manner of operating an apparatus does not differentiate an apparatus claim from the prior art, if the prior art apparatus teaches all of the structural limitations of the claim. See *Ex Parte Masham*, 2 USPQ2d 1647 (BPAI 1987) (see MPEP § 2114).



Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Krulevitch et al. in view of Palti (U.S. Pat. No. 5,474,552 A). Krulevitch et al. do not specifically teach the further incorporation of a detections means within the device. Krulevitch et al. do that their disclosed implantable microfluidic apparatus may be utilized with individuals requiring controlled drug delivery and the periodic administering of drugs (see col. 8, lines 11 – 28). Palti teaches an implantable apparatus comprising a sensor and a drug delivery pump, which is utilized in monitoring and maintaining the concentration of glucose in a person within a predetermined range (see Abstract). As a result, a person of ordinary skill in the art would have recognized the suitability of incorporating a sensor or detection means, as taught by Palti, within the apparatus of Krulevitch for the intended purpose of continuous monitoring and control of glucose

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within a person (see MPEP § 2144.07). Furthermore, as evidenced by Palti, a person of ordinary skill in the art would accordingly have had a reasonable expectation of success of incorporating a detection means within an implantable microfluidic apparatus. The Courts have held that the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (see MPEP § 2143.02).

Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate a detection means within the apparatus of Krulevitch et al. in order to provide a means for effective continuous monitoring and control.

2. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krulevitch et al. in view of Palti, as applied to claim 14 above, and further in view of Weigl et al. (U.S. Pat. No. 5,948,684 A). Krulevitch et al. in view of Palti do not specifically teach the further incorporation of a detection means comprising a T-sensor. Weigl et al. do teach the use of a T-sensor in glucose detection (see col. 14, lines 32 – 58). As a result, a person of ordinary skill in the art would have recognized the suitability of incorporating a T-sensor, as taught by Weigl et al., within the apparatus of Krulevitch and Palti for the intended purpose of facilitating effective glucose detection (see MPEP § 2144.07). Furthermore, as evidenced by Weigl et al., a person of ordinary skill in the art would accordingly have had a reasonable expectation of success of utilizing a T-sensor for glucose detection. The Courts have held that the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (see MPEP § 2143.02). Therefore, it would have been obvious to a person of

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ordinary skill in the art to incorporate a T-sensor detection means within the apparatus of Krulevtich et al. and Palti in order to provide a means for effective continuous monitoring and control. Regarding claim 16, Weigl et al. teach that the T-sensor relies on a diffusion separation process to effect sample detection and analysis (see col. 7, lines 29 – 36).

Conclusion

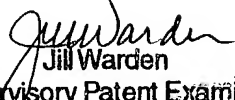
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Yager et al. teach a microfabricated diffusion-based T-sensor. Saylor et al. teach an implantable microfluidic apparatus for controlled drug delivery. Harpstead et al. teach implantable drug infusion techniques. Labbe et al. teach an implantable pump system.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines, Ph.D. whose telephone number is (571) 272-1263. The examiner can normally be reached on Monday - Friday (11:30 AM - 8 PM EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Jill Warden
Supervisory Patent Examiner
Technology Center 1700